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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,775	01/08/2002	Richard A. Gatti	UC081.001A	5310

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,775

Applicant(s)

GATTI ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,10-19,21 and 23-31 is/are pending in the application:
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5,10-13,15 and 16 is/are allowed.
- 6) ☒ Claim(s) 14,17-19,21 and 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to an amendment filed 6/3/04. Claims 3, 4, 6-9, 20 and 22 have been canceled. Claims 1-3, 7, 9-10, 17-18, 21 and 23 have been amended. Claims 1, 10, 23 and 27 have been amended. Claims 28-31 are new. Claims 1, 2, 5, 10-19, 21 and 23-31 are pending.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicant's amendment and therefore, this action is not final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

The limitation that in L3 cells, "ATM protein is produced at levels greater than 2 μg per 8×10^6 host cells" has been added to the claims. Applicant has indicated that support for this limitation is found on page 11, lines 23-25. This passage teaches that

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ATM from HeLa cells can produce ATM “at levels greater than 5 μg (10 μg , 20 μg , 30 μg) per 8×10^6 host cells”. HeLa cells are ATM positive and therefore the yield from these cells maybe greater than those found in an ATM deficient cell line such as L3 cells. Therefore, it is unclear what yields can be expected from L3 cells according to the instant specification. The examiner has been unable to find literal support in the originally filed specification ATM production from L3 “at levels greater than 5 μg (10 μg , 20 μg , 30 μg) per 8×10^6 host cells”. Therefore, the limitation of L3 producing “levels greater than 5 μg (10 μg , 20 μg , 30 μg) per 8×10^6 host cells” is impermissible NEW MATTER.

Claims 17-19, 21 and 23-31 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Applicants recite a method of producing recombinant ATM in mammalian cells in which functional ATM protein is produced at levels greater than 5 μg (10 μg , 20 μg , 30 μg) per 8×10^6 host cells. Applicants recite a broad genus of host cells for ATM production.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a

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combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The instant invention is drawn to a method of producing recombinant ATM in mammalian cells. In the instant case, the specification discloses two cell lines, L3 ATM deficient cells and HeLa cells ATM expressing cells, for the production of ATM. Upon infection of HeLa cells with a vaccinia viral vector expressing ATM, it is stated that 0.3-0.5 $\mu\text{g}/\mu\text{l}$ of ATM is purified and more preferably 2 μg per 300 grams of tissue and at levels greater than 5 μg (10 μg , 20 μg , 30 μg) per 8×10^6 host cells. L3 (ATM deficient) cells are infected with vaccinia viral vector expressing ATM but the levels of ATM are not indicated. Instead, L3 cells are used for the detection of ATM in Western blot analysis and in *in vitro* kinase assays (page 9, line 8- page 10, line 2). The disclosure only teaches that yields of greater than 2 μg per 300 grams of tissue are attained when vaccinia viral vector is used in HeLa cells. The prior art with the exception of Chan et al, which teaches purification of 2 μg of endogenous ATM from 300 grams of non-transfected placenta tissue (see page 3, line 9-13 of the instant specification) does not teach yield per cell number or weight from mammalian cells. By disclosing HeLa yields of ATM from HeLa cells, the applicants have not reduced to practice the claimed invention and the relationship between structure of the host cell and protein production is unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

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Conclusion

Claims 1, 2, 5, 10-13 and 15-16 are allowed

Claims 14, 17-19, 21 and 23-31 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

August 19, 2004


GERRY LEFFERS
PRIMARY EXAMINER